Remarks

The office action identified several deficiencies with respect to the filing of the present divisional reissue application, and the claims have been rejected under 35 U.S.C. §§112 and 102. Applicant herein submits its response.

Claim Amendments

The claims previously presented have been amended in certain respects, as follows:

Amended Claim	Amendment
68, 76, 77, 82, 90, 91, 96, 103	Changed "edge" to "edge surface"
78,92	Changed "opposed sides of the test strip" to "opposed sides of the capillary channel"
81, 86, 95	Changed "edge" to "edge surface", and changed "opposed sides of the test strip" to "opposed sides of the capillary channel"

Assent of Assignee and Reissue Oath/Declaration

Applicant herewith submits the Consent of the Assignee and a Statement Under 37 CFR 3.73(b). Applicant herewith submits also the declarations of inventors Surridge and McMinn. Applicant is obtaining the declaration for Crismore and will submit same in a supplemental response to the office action.

Claim Rejections Under §112

Claims 68-104 were rejected under §112 on two bases. One basis was the use of the phrase "at least working and counter electrodes", and the indication that it was believed that the term should refer to "at least one working electrode". Applicant understands that one proper format for referring to working and counter electrodes would be to refer to "at least one working electrode and at least one counter electrode". However, applicant submits that it

would be equally accurate to refer to "at least two electrodes", or more particularly in this case, to refer to "at least working and counter electrodes".

The claims were also rejected for an asserted failure of the disclosure to disclose a "fill line". In response, applicant submits the following comments and the subsequent claim table showing the specification support for the claims, including specific reference to the disclosure of a "fill line" as called for in the claims. Applicant therefore believes that the new claims are sufficiently supported under §112.

General support for the new claims is found throughout the specification and the drawings. Attention is directed to the Abstract (lines 11-15), the Figures (particularly Figures 1, 3i and 5), and the disclosure found at column 1, line 61 to column 2, line 14; column 4, lines 1-48; and column 8, line 26 to column 9, line 9. In addition to these general portions of the specification, support for the claims can be found as follows:

General claim features:	Support:
68. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising: a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel extending from the sample application port to at least the vent;	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface;	Col. 3, lines 39-42: "In the test strip . . . . electrically conductive track 5 would be the working electrode, and electrically conductive track 6 would be a counter electrode or reference electrode."
a test reagent adjacent at least at the working electrode	Col. 4, lines 1-4: "Second opening 11 exposes a different portion of conductive tracks 5 and 6 for application of test reagent 12 to those exposed surfaces of tracks 5 and 6."

visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid, transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including said working electrode and at least a portion of said counter electrode,	Abstract, lines 11-15: ". . . identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 36-36: "Further, insufficient sample may also be drawn into the capillary reaction chamber, thereby resulting in an inaccurate test result." Col. 1, line 60 to col. 2, line 4: "The window defines the minimum sample amount, or dose, required to accurately perform a test, and therefore, represents a visual failsafe which reduces the chances of erroneous test results due to underdosing of a test strip." Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18. The orthogonal dimension of window 18 should expose the entire width of the working electrode 5. Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered. This coverage of the electrodes by the test sample is important to achieving an accurate test in a capillary-fill electrochemical biosensor. This visual confirmation of sufficient dosing of the test strip provides a safeguard against erroneous test results due to undetected underdosing of the test strip."
said visualization means further includes a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.	Abstract, lines 11-15: "The roof of the capillary test chamber includes a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test." Col. 1, lines 63-67: "The second new feature is a transparent or translucent window which operates as a 'fill to here' line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the

	test chamber to accurately perform a test." Col. 8, line 63 to col. 9, line 4: "it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered with sample and that a sufficient part of the counter or reference electrode 6 is also covered."
69. The test strip of claim 68 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	Col. 8, lines 27-29: "A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
70. The test strip of claim 69 in which the fill line extends at a location between the working electrode and the vent.	See Figure 3i (back edge of window 18 is between working electrode 5 and vent 4).
71. The test strip of claim 70 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	See claim 69.
72. The test strip of claim 68 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.	See Figures 3i and 5. Also see: Col. 8, lines 26-31: "The window is positioned and dimensioned so that when the roof is affixed to surface 8, it will align with opening 11 as shown in FIG. 3h." Col. 8, line 52 to col. 9, line 9: "Finally, roof 13 is placed onto surface 8. (See FIG. 3h) It is at this stage that the transparent or translucent window 18 defined by the absence of printed ink on roof 13 must align with opening 11 as shown in FIG. 3h." Figures 3h and 31.
73. The test strip of claim 72 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.	Col. 8, lines 26-31: "Preferably, roof 13 is made of MELINEX 561 polyester foil, having a thickness of 5 mil. A substantially opaque ink is printed on first surface 16 in pattern 27 such that window 18 remains transparent or translucent."
74. The test strip of claim 73 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.	Col. 8, line 52 to col. 9, line 9: "The dimensions of transparent or translucent window 18 should be chosen such that a substantial fraction of the width (greater than about 75%) of the underlying capillary channel is visible through window 18.
75. The test strip of claim 68 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first	See Figures 3i and 5. Also see: Col. 4, lines 36-45: "Second surface 17 of roof 13, the edges of opening 11, and first surface 22 of insulating substrate 1 (and

substrate and the roof defining the capillary channel.	conductive tracks 5 and 6 affixed to first surface 22 of substrate 1) define a capillary testing chamber." Col. 8, lines 61-64: "Therefore, when a sample, such as blood, is introduced into the capillary test chamber, through sample application port 20, it is possible for a user of reasonable acuity to determine if the window is entirely full of sample."
76. The test strip of claim 75 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge surface of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.	See Figures 3i, 4 and 5, and associated description in the specification.
77. The test strip of claim 75 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes.	See Figure 3i and col. 4, lines 35-41 and col. 8, lines 26-64.
78. The test strip of claim 77 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.	See claim 77.
79. The test strip of claim 78 in which the opaque portions are defined by the roof.	See col. 8, lines 27-31.
80. The test strip of claim 75 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the	See col. 8, lines 27-64.

capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material, whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the fill line.	
81. The test strip of claim 80 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, and the fill line extends across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.	See claim 72.
82. An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising: a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge surface, the capillary channel extending from the sample application port at least to the vent; at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge surface; and a test reagent adjacent at least the working electrode; said strip body defining a viewing area allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode, the viewing area being positioned and dimensioned such that blood introduced to the capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test, said strip body further including a fill line extending across the viewing area at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test.	See claim 68.
83. The test strip of claim 82 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	See claim 69.
84. The test strip of claim 83 in which the fill line extends at a location between the working electrode and the vent.	See claim 70.
85. The test strip of claim 84 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	See claim 69.
86. The test strip of claim 82 in which said strip body includes opposed sides of the capillary channel, the sides	See claim 77.

being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.	
87. The test strip of claim 86 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.	See claim 78.
88. The test strip of claim 87 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.	See claim 74.
89. The test strip of claim 82 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.	See claim 75.
90. The test strip of claim 89 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge surface of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.	See claim 76.
91. The test strip of claim 89 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes.	See claim 77.
92. The test strip of claim 91 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes, the fill line extending across the capillary channel in an orientation orthogonal to the opposed sides of the capillary	See claim 78.

channel.	
93. The test strip of claim 92 in which the opaque portions are defined by the roof.	See claim 79.
94. The test strip of claim 89 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material, whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the fill line.	See claim 80.
95. The test strip of claim 94 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge surface, to at least one of the electrodes, and the fill line extends across the capillary channel in an orientation orthogonal to the opposed sides of the capillary channel.	See claim 81.
96. An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising: a strip body including an edge surface extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge surface, the capillary channel extending from the ample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent; at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge surface; a test reagent received within the test area of the capillary channel and adjacent at least the working electrode; said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area; said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel	See claim 68.

needed to be filled to conduct an accurate test; and a fill line extending across the capillary channel at a location intermediate the length of the capillary channel at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test. wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.	
97. The test strip of claim 96 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	See claim 69.
98. The test strip of claim 96 in which the fill line extends at a location between the working electrode and the vent.	See claim 70.
99. The test strip of claim 98 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	See claim 69.
100. The test strip of claim 96 in which the fill line extends at a location between the test area and the vent.	See claim 70.
101. The test strip of claim 100 in which said fill line is formed by an opaque portion overlying a portion of the capillary test chamber.	See claim 69.
102. The test strip of claim 96 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the fill line the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.	See claim 68.
103. The test strip of claim 96 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge surface to the electrodes.	See claim 73.
104. The test strip of claim 96 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the fill line the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.	See claim 68.

Applicant submits that it is apparent from the foregoing claim table, and particularly the quoted passages from the specification, that the application sufficiently discloses the concept claimed herein, that being the provision of a line demarcated on a test strip which indicates to where the blood sample must fill in order to conduct a test. More particularly, the specification clearly discloses the concept of surrounding the capillary channel such that it is

apparent to the user that the area viewable as the blood fills the capillary channel is the area that must be filled for the test strip to be adequately dosed. This is in contrast to prior art devices, discussed in more detail hereafter, for which the user may be able to see blood sample entering into the test strip, but the user can not distinguish whether the correct area, and the total required area, of the test strip is filled at the time of testing. If the user can see too much of the strip interior, to the extent that the user can not tell which portions of that interior need not be filled, then the strip does not convey to the user whether the strip has been adequately dosed.

Patentability Over the Art

As a preliminary comment, applicant notes that all of the devices described in the cited patent references are distinguishable from the present invention in the respect that they fail to disclose or suggest a capillary-fill, electrochemical test strip in which the movement of a blood sample to a fill line can be visualized to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area, such that the test results can be accurate.

Electrochemical test strips are unique as compared to test strips involving color change, fluorescence or other reaction indicators involving direct viewing of the test site. Those test strips naturally have an area for visualizing the test area because the results are detected in that manner. Such test devices will therefore provide some amount of visibility to the test area.

The present claims are limited, however, to capillary-fill devices in which a transparent or translucent portion overlies the internal capillary chamber. Moreover, this transparent or translucent portion is indicated to be a "solid" material. The claims are

therefore specifically distinguished from prior art devices in which there is simply an opening that is exposed to the outside without a solid material providing visualization of a blood sample as it fills into the interior capillary chamber.

Referring to the cited art, applicant first notes that all of the references have a common failing with respect to anticipation of the present claims, and that is the fact that a blood sample can not be viewed through a solid, transparent or translucent material as the sample fills a capillary channel inwardly from the edge of the test strip. The Diebold et al. patent 5,437,999, for example, has been cited for showing a device with cut out portions, a vent and reagents associated with the electrodes. However, there is no teaching of a test strip which has a solid, transparent or translucent portion overlying the capillary chamber, nor is there a suggestion for a fill line used in conjunction with such a solid portion. The Diebold '999 device is formed by sandwiching a spacing layer 43 between top and bottom electrode support layers (see 11 and 48 in Fig. 5), with cutout 49 defining the capillary channel. However, there is nothing in Diebold '999 which indicates that either the top or bottom layer is transparent or translucent, and indeed it shows the capillary channel as hidden (see dashed lines in Fig. 6) by the outer layers. Thus, there is no solid, transparent or translucent material through which filling of the capillary channel can be viewed by the user.

Hodges '102 and '420 also fail to show a viewable capillary channel. Both show a sandwich-type test strip in which the interior, circular chamber is hidden by the outer layers. The only viewable portion is arguably the notches (9 in '102 and 16 in '420), but those do not represent the interior capillary channel, and that is not the area which the sample must fill for the strip to be ready to conduct a test. There is nothing in either of the Hodges references that

operates anything akin to a fill line or a viewing area representing the area required to be filled to conduct a test.

The Charlton '031 patent shows a test strip having a base 36 and a lid 46, with the lid being embossed to form a concave space 48 to receive a blood sample. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent, and does not identify a fill line.

Ikeda '895 similarly discloses a sandwich-type test strip with top and bottom layers 6 and 9 and an interior chamber 11-11b. However, there is no indication or showing that any portion of the layers 6 or 9 are transparent or translucent. Yoshioka '103 has a similar sandwich-type design, and fails to show that any portion of the outer layers 1 or 4 are transparent or translucent.

In Seshimoto '445, the device includes a bottom plate 21 and a top plate 18, with testing electrodes 11a-11c received in an interior passage 14. Sample is received at top opening 12 and then directed down through passage 13 to the interior 14. There is nothing in Seshimoto '445 to suggest that any part of plate 21 or plate 18 is transparent or translucent to allow viewing of the sample as it moves along interior passage 14.

Columbus '457 is similar to Seshimoto '445 in providing a device in which sample is received through a top opening 42 or 42' and conveyed through a capillary channel defined by surfaces 34 and 36 (see column 3, lines 31-65). There is no indication that the top 30 (including surface 34) or the bottom 32 (including surface 36) is transparent or translucent.

Galen et al. 5,695,949, and its divisional 6,027,692, both disclose a top-dosing strip with openings 6, 7 and 11 extending from the top substrate through to the bottom substrate.

There is no solid, transparent or translucent portion to allow blood to be visualized as it fills a capillary channel, and no fill line to indicate when sufficient filling has occurred.

In comparison to the cited art, the present invention provides a uniquely advantageous design for a capillary fill test strip in which the filling of the strip is viewable in a manner that the user can determine if adequate filling has occurred to conduct a test. As the Examiner noted in the recent Office Action at page 2 (second and third line from the bottom), it is an aspect of the present invention to provide "an area where the user can see if the proper amount of sample is present." This is not accomplished in the cited art.

Independent claim 68 describes a capillary fill test strip including a visualization means "for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test." That means includes a "solid, transparent or translucent viewing material" extending along the channel, and a "fill line extending across the capillary channel at a location intermediate the length of the capillary channel." The fill line is referenced in the specification, for example, at column 1, lines 63-67, which describes that the window "operates as a 'fill to here' line, thereby identifying when enough test sample . . . has been added to the test chamber to accurately perform a test." This line is evident, for example, in Figure 3i where the window 18 overlies the capillary channel, and portions of the working and counter electrodes 5 and 6. As blood enters the channel in the area of the notch 15, it flows inwardly (downwardly in Figure 3i) by capillary action toward and beyond the electrodes. The opaque coloring which defines the viewable portion 18 includes parallel sides extending along the channel, and an end line running perpendicular to the direction of capillary movement (i.e., horizontally in Figure 3i). The user is able to watch the blood flow through the channel by viewing through the

translucent or transparent portion surrounded by the opaque coloring. When the window 18 appears full, then the user knows that a sufficient amount of blood has been dosed to the test strip to conduct a test. The user can ascertain this, even though the user may not know what structures/areas are viewable – it is sufficient to see the blood move all the way to the end line.

Note also that the viewable area shown in Figure 3i includes the working electrode 5 and a portion of the counter electrode 6. Thus, the "fill to here" line referenced at col. 1, lines 63-66 is positioned such that the blood will only reach the line if/when it has contacted both the working and counter electrodes. It will be appreciated by those in the art that the profile of the "front" of the blood sample as it flows into the capillary channel will not likely be a straight line, but rather may be either convex or concave relative to the direction of travel. In any event, the fill to here line is operative whether the entire window is filled with blood or not – and thus the reference in the specification to this providing a fill to here line.

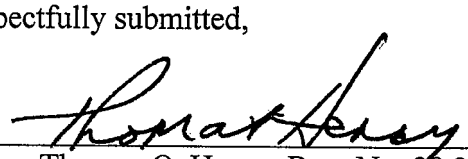
Independent claim 82 differs in that it refers to a viewing area "positioned and dimensioned such that blood introduced to the capillary channel . . . and filling the viewing area . . . is required for the test strip to have a sufficient blood sample to conduct a test." Claim 82 further provides for a fill line "extending across the viewing area . . . at a position such that movement of the blood sample to the fill line indicates sufficient filling of the test strip for conducting a test." As previously described, these features are shown and described in the specification – both in the text and in the drawings.

In independent claim 96, there is provided a test strip including a "solid, transparent or translucent viewing material overlying at least a portion of the capillary channel" with "opaque portions defining a fill area viewable through the viewing material" such that the fill

area comprises "an area of the capillary channel needed to be filled to conduct an accurate test." Also included is a fill line which similarly indicates sufficient filling of the test strip.

Applicant submits that the present invention is therefore seen to be uniquely distinguished from the prior art. The independent claims clearly define over the art, and the dependent claims add further limitations which distinguish the present invention over the prior art. Reconsideration of the application and allowance of claims 68-104 is therefore respectfully requested. The examiner is requested to contact the undersigned by telephone if it appears that issues may be more readily resolved leading to allowance of this application.

Respectfully submitted,

By: 

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